NOV 0 5 2001

K002937

510(k) SUMMARY
Albert Browne Ltd.
TST Control Integrator for Steam Sterilizers

1. SUBMITTER NAME AND ADDRESS

Mr. Alan Charlton
Albert Browne Ltd.
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Date Prepared: November 1, 2001

2. DEVICE NAME

Proprietary Name:	TST Control Integrator for Steam Sterilizers
Common/Usual Name:	Chemical indicator
Classification Name:	Physical/chemical sterilization process indicator

3. PREDICATE DEVICE

TST Control Integrator for Steam Autoclave (K965154)

4. INTENDED USE

The TST Control Integrator for Steam Sterilizers (TST Control Integrator) is a chemical integrator that can be used to monitor sterilization efficacy in vacuum-assisted 132°C, 134°C, and 135°C steam sterilization cycles. The TST Control Integrator changes color from yellow to blue.

5. DEVICE DESCRIPTION

The proposed TST Control Integrator is identical to the TST Control Integrator described in K965154. Like the predicate TST Control Integrator, the proposed TST Control Integrator is a 22 mm x 143 mm strip of polypropylene-coated casting paper, with the chemical indicator ink located in a 12 mm circle on one

end of the strip. The proposed and predicate devices indicate exposure to specific combinations of exposure time and temperature (see Table 1) through a visible color change in the indicator ink.

Table 1. Exposure Conditions Required for Color Change

Time (min.)	Temperature (°C)
3.0	132
2.45	134
2.2	135

6. TECHNOLOGICAL CHARACTERISTICS

The integrator changes color due to a chemical interaction in the indicator ink that occurs when the integrator is exposed to steam at the stated values for time and temperature. The proposed TST Control Integrator, including the formulation of the indicator ink and the physical characteristics of the strip, is identical to the TST Control Integrator described in K965154.

7. PERFORMANCE TESTING

Data was provided that demonstrates that the TST Control Integrator meets the requirements for Class 5 indicators as defined in clauses 9.1 and 9.3 of ANSI/AAMI ST60-1996 "Sterilization of health care products – Chemical indicators – Part 1: General Requirements" for 132°C, 134°C, and 135°C sterilization cycles. The TST Control Integrator reports a FAIL at an exposure time 16% less, or a temperature 1°C less, than the stated values in Table 1. The conditions required to produce a color change exceed those required to inactivate $>10^5$ spores in biological indicators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 5 2001

Albert Browne Limited
C/O Ms. Cynthia J.M. Nolte
Medical Device Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002937
Trade/Device Name: TST Control Integrator for Steam Sterilizers
Regulation Number: 880.2800
Regulation Name: Chemical Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 4, 2001
Received: September 6, 2001

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: TST Control Integrator for Steam Sterilizers

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002937

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109